CLAIMS

1. An oral immediate release dosage form comprising *N*-[5-methyl-8-(4-methylpiperazin-1-yl)-1,2,3,4-tetrahydro-2-naphthyl]-4-morpholinobenzamide as the active compound, in the form of the free base or pharmaceutically acceptable salts, thereof, at least one disintegrant and/or at least one soluble filler, with or without one binder, and optionally other excipients.

2. An oral immediated release dosage form comprising

N-[5-methyl-8-(4-methylpiperazin-1-yl)-1,2,3,4-tetrahydro-2-naphthyl]-4-morpholinobenzamide	3 to 90 % (w/w)
Disintegrants	0 to 20% (w/w)
Soluble fillers	0 to 80% (w/w)
Binders	1 to 10 % (w/w)
Other excipients	up to 100% (w/w)

3. The oral immediated release dosage form according to claims 1 or 2, wherein the active compound is (*R*)-*N*-[5-methyl-8-(4-methylpiperazin-1-yl)-1,2,3,4-tetrahydro-2-naphthyl]-4-morpholinobenzamide.

4. The oral immediated release dosage form according to any one of claims 1 to 3, wherein the salt of (*R*)-*N*-[5-methyl-8-(4-methylpiperazin-1-yl)-1,2,3,4-tetrahydro-2-naphthyl]-4-morpholinobenzamide is (*R*)-*N*-[5-methyl-8-(4-methylpiperazin-1-yl)-1,2,3,4-tetrahydro-2-naphthyl]-4-morpholinobenzamide monohydrobromide.

5. The oral immediate release dosage form according to any one of claims 1 to 4, wherein the disintegrants are selected from the group consisting of croscarmellose sodium, sodium starch glycollate, crospovidone, microcrystalline cellulose, low substituted hydropropyl cellulose, soy polysaccharide, starch, alginic acid, sodium alginate, polacrillin potassium, magnesium aluminium silicate and amberlite resins.

The invention further relates to the oral immediate release dosage form wherein the disintegrant is croscarmellose sodium.

Excipients enhancing the dissolution in a neutral or acid aqueous environment, such as sodium- or potassium carbonate or –bicarbonate alone or in combination with citric acid, ascorbic acid or tartaric acid, may also be used in the oral immediate release dosage form.

6. The oral immediate release dosage form according to claim 5, wherein the disintegrant is croscarmellose sodium.

7. The oral immediate release dosage form according to any one of claims 1 to 4, wherein the soluble fillers are selected from the group consisting of lactose, sucrose, dextrose, mannitol, sorbitol, xylitol, maltose, maltodextrin, maltitol, lactitol, fructose, dextrates and a number of inorganic salts.

8. The oral immediate release dosage form according to any one of claims 1 to 4, wherein the soluble fillers is mannitol.

9. The oral immediate release dosage form according to any one of claims 1 to 8, wherein the binders are selected from the group comprising of hydroxypropyl cellulose, microcrystalline cellulose, polyvinylpyrrolidone, gelatine, polyethylene glycol, glycerylbehenate, glycerylmonostearate, ethylcellulose, ceratonia, hydroxy propylmethylcellulose, hydroxy ethylcellulose, polydextrose, polyethyleneoxide, zein, carboxy polymethylene and carnauba wax or a mixture thereof.

10. The oral immediate release dosage form according to claim 11 wherein the binder is polyvinylpyrrolidone.

11. The oral immediate release dosage form according to any one of claims 1 to 10, wherein the other excipients are lubricants, fillers and flow condition agents.

12. The oral immediate release dosage form according to claim 11, wherein the lubricants are selected from the group of magnesium stearate, calcium sterarate, zink stearate, carbomer,

sodium stearyl fumarate, glyceryl monostearate, poloxamer, sodium benzoate, sodium lauryl sulphate, stearic acid, polyethylene glycol and talc.

13. The oral immediated release dosage form according to claim 11, wherein the fillers are selected from the group of calcium phosphates, starches, microcrystalline cellulose, calcium sulphate, polyethylene glycol, calcium carbonate, magnesium carbonate, magnesium oxide and kaolin.

14. The oral immediate release dosage form according to claim 11, wherein the flow condition agent is colloid silicon dioxide.

15. The oral immediate release dosage form according to any one of claims 1 to 14, wherein the ratio of active compound to disintegrants is from 6:1 to 1:2, preferably from 3:1 to 1:1.

16. The oral immediate release dosage form according to any one of claims 1 to 15, where in the weight ratio of active compound to binders may be from 8:1 to 1:2.

17. The oral immediate release dosage form according to any one of claims 1 to 16, wherein the dosage form is in the form of a capsule or a tablet.

18. The oral immediate release dosage form according to any one of claims 1 to 17, whereby the dosage form has a mean dissolution profile *in vitro*, in 50 nM acetate buffer, pH of 5.5, using USP Paddle method at 75 rpm, such that at least 85 % of the active compound is released within 30 minutes.

19. Processes for the manufacture of an oral immediate release dosage form according to any one of claims 1 to 17 characterized by,
Method A, comprising the steps:
Ai) mixing the active compound with the disintegrant, soluble fillers, binders and optionally lubricants, fillers and other excipients,
Aii) forming the obtained dry powder mixture into a suitable solid dosage form,

Or,

Method B, comprising the steps:

Bi) mixing the active compound with the disintegrant, soluble filler and optionally binders and other excipients,

Bii) granulating said mixture,

Biii) optionally drying or cooling the obtained granules,

Biv) mixing the granules with other excipients,

Bv) filling the obtained dry powder mixture into suitable solid dosage form.

20. Use of an oral immediate release dosage form according to any one of claims 1 to 17 for use in therapy.

21. The use according to claim 20 for the prevention and/or treatment of disorders in the central nervous system and related disturbances.

22. The use according to claim 20 for the prevention and/or treatment of mood disorders, anxiety disorders, personality disorders, obesity, anorexia, bulimia, premenstrual syndrome, sexual disturbances, alcoholism, tobacco abuse, autism, attention deficit, hyperactivity disorder, migraine, memory disorders, pathological aggression, schizophrenia, endocrine disorders, stroke, dyskinesia, Parkinson´s disease, thermoregulatory disorders, pain and hypertension.

23. The use according to claim 20 for the prevention and/or treatment of major depressive disorder.

24. The use according to claim 20 for the prevention and/or treatment of urinary incontinence, vasospasm and growth control of tumors.

25. The use according to claim 20 for the prevention and/or treatment of 5-hydroxytryptamine mediated disorders.

26. Use of an oral immediate release dosage form according to any one of claims 1 to 17, in the manufacturing of a medicament for prevention and/or treatment of disorders in the CNS and related disturbances.

27. A method for prevention and/or treatment of disorders in the central nervous system and related disturbances, comprising administering to a mammal in need of such prevention and/or treatment oral immediate release dosage form according to any one of the claims 1 to 17, effective for said prevention and/or treatment.

28. An oral immediate release dosage form according to any one of claims 1 to 17, whereby the dosage form upon administration provides t_{max} for (*R*)-*N*-[5-methyl-8-(4-methylpiperazin-1-yl)-1,2,3,4-tetrahydro-2-naphthyl]-4-morpholinobenzamide monohydrobromide between 3 to 7 hours.

29. Use of disintegrants in preparing an oral immediate release dosage form of an active compound that forms an agglomerate upon contact with water, at acidic, neutral or basic pH.